

AUG 30 1996

510(k) Summary

DMS will provide a 510(k) Summary and allow for the "public" to request this information.

We have taken the terminology from the Reference Manual-"Premarket Notification 510(k): Regulatory Requirements for Medical Devices" (FDA 92-4158).

*Summary*

Del Medical Systems feels the S-41 and S-41S Video Imaging System are substantially equivalent to the MSV-2000 marketed by Del Medical Systems under K942924 and also to many legally marketed devices already in commercial distribution such as: Storz, Olympus, MP Video, Richard Wolf, Medical Dynamics and Dyonics, just to name a few. Medical Dynamics markets their camera in conjunction with a laparoscope under K903339.

The design of the S-41 and S-41S is virtually identical to the comparative devices, which are listed and displayed in Exhibits 2 and 3. Since the design is comparable, technology virtually identical, the specifications very similar, and the intended use the same, DMS feels that these minor differences have no impact on the safe use and/or effectiveness of the device.

For information purposes and completeness, Del Medical Systems has also incorporated other legally marketed devices in this filing to illustrate the wide, general use of similar other devices. This wide use has led to the safe use of the device in many practitioner's hands.